K092299

AUG 07 2009

510(k) Summary

TrailBlazer™ Support Catheter

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R § 807.92.
Applicant	ev3 Inc.
Submitter	ev3 Inc. 9600 54th Ave. N Plymouth, MN 55442 Tel: 763-398-7000 Fax: 763-591-3248
Contact Person	David Robertson Regulatory Affairs Associate
Date Prepared	July 16, 2009
Device Trade Name	TrailBlazer™ Support Catheter
Device Common Name	Catheter, Support
Classification Name	Catheter, Percutaneous (21 CFR 870.1250), Product Code DQY
Classification Panel	Cardiovascular
Predicate Devices	Spectranetics Quick-Cross™ Support² Catheters (K072750) Vascular Solutions Minnie™ Support Catheter (K082337)
Intended use	TrailBlazer™ Support Catheters are percutaneous, single lumen catheters designed for use in the peripheral vascular system. TrailBlazer™ Support Catheters are intended to guide and support a guide wire during access of the vasculature, allow for wire exchanges and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.
Device Description	The TrailBlazer™ Support Catheter is an over-the-wire (OTW) single lumen catheter with an atraumatic tapered tip. The catheter system is offered in 9 models that are 0.014", 0.018", and 0.035" guidewire compatible and have working lengths of 65 cm, 90 cm, 135 cm, 150 cm. The distal catheter shaft has three radiopaque markers that aid in positioning the catheter. The distal 40 cm portion of the catheter has a hydrophilic coating. The manifold provides a proximal lumen which transitions to the catheter shaft and terminates at the distal tip. This lumen is used to pass the catheter over a guidewire. All models are 5 Fr compatible.

Performance data	Bench testing was performed to support a determination of substantial equivalence. Results from this testing provide assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use.
Summary of Substantial Equivalence	The TrailBlazer™ Support Catheter has the following similarities to the predicate devices: • Similar fundamental scientific technology • Similar operating principle • Similar flow rate • Similar crossing profiles • Similar catheter lengths
Conclusion	Based on the similar indications for use, technological characteristics, and performance testing, ev3 believes the TrailBlazer™ Support Catheter is substantially equivalent to the Spectranetics Quick-Cross Support Catheter (K072750) and Vascular Solutions Minnie Support Catheter (K082337).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

ev3 Inc.
c/o Mr. Mark Job
Reviewer
Regulatory Technology Services
1394 25th Street NW
Buffalo, MN 55313

AUG 07 2009

Re: K092299
Trade/Device Name: Trailblazer Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (Two)
Product Code: DQY
Dated: July 27, 2009
Received: July 31, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K092299

Device Name: TrailBlazer™ Support Catheter

Indications for Use:

TrailBlazer™ Support Catheters are percutaneous, single lumen catheters designed for use in the peripheral vascular system. TrailBlazer™ Support Catheters are intended to guide and support a guide wire during access of the vasculature, allow for wire exchanges and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Feldman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092299